

Serial No.: 10/075,970

REMARKS

Claims 1, 3-7 and 9-21 are pending herein, claims 8 and 22-45 having been cancelled without prejudice or disclaimer.

Claim Rejection under 35 U.S.C. §103(a)—Datta

Claims 1, 3-21 and 45 are rejected under 35 U.S.C. §103(a) as being unpatentable over Datta et al., US 6,338,739 (Datta). Applicant respectfully traverses this rejection and its supporting remarks.

For example, independent claim 1 is presently directed to an implantable or insertable medical device comprising a biodegradable inner core material and a biodegradable covering material at least partially covering the inner core material, which, after insertion or implantation into a patient, becomes decreasingly rigid and increasingly biomechanically compatible with body tissue in contact with the device over time. The biodegradable inner core material is selected from a metallic material and a ceramic material.

Datta describes a biodegradable stent made from a biodegradable fiber having an inner core and outer layer. *See* Datta Abstract. The inner core has a first degradation rate and the outer layer has a second degradation rate. *Id.* However, as recognized by the examiner, the invention of claim 1 differs from Datta at least in that Datta does not disclose a biodegradable inner core material selected from a metallic material and a ceramic material. To make up for this deficiency in Datta the examiner argues that the use of these materials would be an "obvious matter of design choice".

The examiner's conclusions that it would have been an obvious matter of design choice to substitute the claimed biodegradable hydrogel, metallic and ceramic materials for the biodegradable polymers of Datta are not well founded. As stated in MPEP 2143.01:

Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art. "The test for an implicit showing is what the combined teachings, knowledge of one of ordinary skill in the art, and the nature of the problem to be solved as a whole would have suggested to those of ordinary skill in the art." *In re Kotzab*, 217 F.3d 1365, 1370, 55 USPQ2d 1313, 1317 (Fed. Cir. 2000). See also *In re Lee*, 277 F.3d 1338, 1342-44, 61 USPQ2d 1430,

Serial No.: 10/075,970

1433-34 (Fed. Cir. 2002) (discussing the importance of relying on objective evidence and making specific factual findings with respect to the motivation to combine references); *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

Indeed, a rejection based on 35 U.S.C. § 103 must rest on a factual basis, and these facts must be interpreted without hindsight reconstruction of the invention from the prior art. In making such a rejection, the examiner has the initial duty of supplying the requisite factual basis and may not resort to speculation, unfounded assumptions, or hindsight reconstruction to supply deficiencies in the factual basis. *See In re Warner*, 379 F.2d 1011, 1017, 154 USPQ 173, 177-78 (CCPA 1967), cert. denied, 389 U.S. 1057 (1968). *See also, In re Zurko*, 258 F.3d 1379, 59 U.S.P.Q.2d 1693 (Fed. Cir. 2001) (deficiencies of references cannot be saved by appeals to "common sense" and "basic knowledge" without any evidentiary support.).

Here, the examiner sets forth, without factual basis or evidentiary support, merely the conclusion that "[o]ne of ordinary skill in the art would have expected Applicant's invention to perform equally well with Datta et al.'s stent because the inner core being made from biodegradable ... metal or ceramic material would perform equally well such that stent would decrease rigid [*sic*] or become more flexible and increasingly biomechanically compatible."

In fact, the biodegradable materials claimed are completely different from those described in Datta. For example, the only materials taught in Datta, for either the inner core or the outer layer, appear to polymers made from monomers selected from lactide, glycolide, para-dioxanone, caprolactone, trimethylene carbonate, and combinations thereof, which polymers are said to soften as a result of hydrolysis. *See Datta* col. 4, lines 23-43, col. 8, line 58 to col. 9, line 6.

As is well known, metals and ceramics provide mechanical properties such as hardness and rigidity that are completely unlike the properties of polymers, including those made from monomers selected from lactide, glycolide, para-dioxanone, caprolactone, trimethylene carbonate, and combinations thereof. Consequently, one of ordinary skill in the art would not have found the use of ceramic or metallic to be an "obvious matter of design choice".

Indeed, it is evident that the examiner has resorted to speculation, unfounded assumptions and hindsight reconstruction in an attempt to make up for the acknowledged deficiencies in Datta. For at least these reasons, it is respectfully submitted that claim 1 is patentable over Datta.

Serial No.: 10/075,970

Claims 3-7 and 9-21 depend from claim 1 and are therefore patentable over Datta for at least the same reasons as is claim 1.

Reconsideration and withdrawal of the rejection of these claims as unpatentable over Datta are requested.

Claim Rejection under 35 U.S.C. §103(a)—Wang

Claims 1, 3-21 and 45 are rejected under 35 U.S.C. §103(a) as being unpatentable over Wang et al., WO 98/56312 (Wang). Applicant respectfully traverses this rejection and its supporting remarks.

The issues here are essentially the same as to those described above in conjunction with Datta, and the case law cited above is applicable here and incorporated by reference.

For example, like Datta, Wang describes stents having inner and outer biodegradable regions which exhibit different time periods of biodegradation. See Wang Abstract. As with Datta above, the examiner recognizes that of claim 1 differs from Wang at least in that Wang does not disclose a biodegradable inner core material selected from a metallic material and a ceramic material. To make up for this deficiency in Wang, the examiner again argues that the use of these materials would be an "obvious matter of design choice," concluding that "[o]ne of ordinary skill in the art would have expected Applicant's invention to perform equally well with Wang et al.'s stent because the inner core being made from biodegradable ... metal or ceramic material would perform equally well such that stent would decrease rigid [*sic*] or become more flexible and increasingly biomechanically compatible."

As with Datta, the inner biodegradable materials described in Wang are polymers and are thus dramatically different from the ceramic and metallic materials claimed.

Hence, as with Datta above, it is evident that the examiner has resorted to speculation, unfounded assumptions, and/or hindsight reconstruction to make up for the acknowledged deficiencies in the prior art reference. For at least these reasons, it is respectfully submitted that claim 1 is patentable over Wang. Claims 3-7 and 9-21 depend from claim 1 and are therefore patentable over Wang for at least the same reasons as is claim 1.

Reconsideration and withdrawal of the rejection of the presently pending claims as unpatentable over Wang et al. are requested.

Serial No.: 10/075,970

CONCLUSION

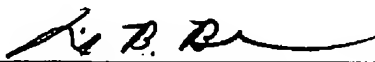
Applicant submits all pending claims are in condition for allowance, early notification of which is earnestly solicited. Should the Examiner be of the view that an interview would expedite consideration of this Amendment or of the application at large, request is made that the Examiner telephone the Applicant's attorney at (703) 433-0510 in order that any outstanding issues be resolved.

FEES

If there are any fees due and owing in respect to this amendment, the Examiner is authorized to charge such fees to deposit account number 50-1047.

Respectfully submitted,


Attorney for Applicant
Mayer & Williams PC
251 North Avenue West, 2nd Floor
Westfield, NJ 07090
Tel.: 703-433-0510
Fax: 703-433-2362


David B. Bonham
Registration No. 34,297

Certificate of Facsimile Transmission

I hereby certify that this document and any document referenced herein is being sent to the United States Patent and Trademark office via Facsimile to: 571-273-8300 on

March 13, 2006

David B. Bonham
(Printed Name of Person Mailing Correspondence)

(Signature)